

### REMARKS

In the instant Action, claims 17, 22, 26 and 31-32 are listed as pending and all claims are rejected. No claims are amended in this reply. Claims 22, 26, 31 and 32 are canceled in this reply. Claims 1-16, 18-19, 20-21, 23-25, 27-30 and 33-40 were previously canceled and amendments to claim 17 were previously presented. Applicant expressly reserves the right to reclaim the canceled subject matter in a subsequent application.

### CLAIM REJECTIONS

#### **1. Claim Rejections – double patenting**

##### **1A. Rejection of claims 17, 22, 26, 31 and 32 under non-statutory obviousness-type double patenting**

At this time, Applicants choose not to address the provisional obviousness-type double patenting rejection of claims 17, 22, 26, 31 and 32 in light of co-pending application serial number 12/074,729 (Prevost).

#### **2. Claim Rejections – 35 U.S.C. § 103(a)**

##### **2A. Rejection of claims 17-19 under 35 U.S.C. 103(a)**

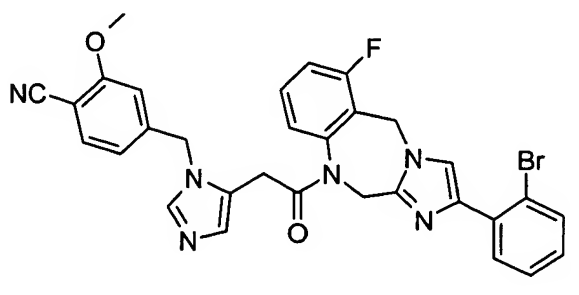
On pages 4-8 of the instant Action, the Examiner has maintained the rejection of claims 17-19 under 35 U.S.C. § 103(a) as being unpatentable over Gordon *et al.* (PCT International Publication WO 00/39130, referred to hereinafter as “Gordon”) in light of Rybak (PCT International Publication WO 01/64197, referred to hereinafter as “Rybak”). In brief, the Examiner alleges that as Gordon discloses the farnesyl transferase inhibitor (FTI) of instant claims 17-19, and as Rybak discloses therapeutic combinations of anthracyclines and FTIs, it would have been obvious to the skilled artisan to provide a pharmaceutical composition comprising an FTI according to Gordon and an anthracycline such as doxorubicin.

The complete details of the Examiner's comments are found on pages on pages 4-8 of the instant Action; these comments are not reiterated in full in this reply.

2B. Claim 17 is not obvious over Gordon in light of Rybak

Applicants again respectfully submit that the invention of instant claim 17 is not obvious over Gordon in light of Rybak. Applicants incorporate all arguments presented in reply to this rejection from the previous replies (mailed September 26, 2007 and February 23, 2009).

Applicants again respectfully point out that claim 17 is now directed to a composition comprising one particular anthracycline and one particular farnesyl transferase inhibitor: doxorubicin and



Applicants again submit that neither Gordon nor Rybak teach or suggest the particular FTI/doxorubicin combination recited in instant claim 17.

Gordon teaches thousands of FTI compounds, forty of which are presented as having been synthesized. The Examiner alleges that because Gordon presents 40 synthesized compounds, then Gordon offers "a list of merely 40 compounds as useful in the invention" (page 6 of the instant Action). Applicants respectfully submit that the Examiner's argument completely ignores the other compounds presented by Gordon. Applicants also respectfully submit that the Examiner gives no reason for excluding the prophetic compounds as useful in the practice of Gordon's invention.

Applicants respectfully submit that the Examiner's argument still does not teach or suggest to the skilled artisan to select one single farnesyl transferase inhibitor. Simply because a compound was synthesized by Gordon does not mean that the remaining

prophetic compounds disclosed are not useful nor does it direct the skilled artisan as to which of the 40 synthesized FTI compounds to select. It is only Applicants' teachings which allow the skilled artisan to select the FTI of instant claim 17.

The Examiner alleges that the "one of ordinary skill in the art would merely have to select this compound" yet the Examiner fails to elucidate the teachings of Gordon that would teach or suggest to the skilled artisan to "merely" select any particular one of the thousands of compounds presented. Gordon does not teach or suggest any advantage of the 40 synthesized compounds as compared to the prophetic compounds disclosed and thus cannot provide any guidance as to one preferred compound over any other compound presented, whether synthesized or not.

Applicants submit that this defect is not cured by Rybak as Rybak discloses even more FTI compounds that were not synthesized. Applicants submit Gordon discloses thousands of prophetic transferase compounds and forty synthesized compounds and Rybak discloses thousands of prophetic transferase compounds. Applicant submits that the Examiner's conclusion that the forty synthesized compounds are the only viable compounds for use is illogical and teaches away from reliance on the Rybak reference as Rybak fails to disclose any synthesized compounds at all. Applicants respectfully submit that the Examiner has provided no legal basis for singling out synthesized compounds versus prophetic compounds as possible choices for the skilled artisan in search of an FTI to combine with an anthracycline. Applicants also respectfully submit that the Examiner has failed to provide any legal basis for alleging that the skilled artisan should only consider synthesized compounds and that the artisan should exclude prophetic compounds when relying on the teachings of the prior art.

Applicants again submit that a reasonable expectation for success must lead to a predictable result and must be more than the presentation of a laundry list of options with no guidance provided as to which option to choose. Applicants again submit that a reasonable expectation of success is not automatically established where the prior art discloses many alternative routes. In the previous reply, Applicants cited *Takeda Chemical v Alphapharm* (492 F.3d 1350, 1356 (Fed. Cir. 2007)), noting that art that

provides many opportunities for erroneous or unsupported combinations and fails to teach success cannot make obvious the clear choice to make.

The Examiner alleges that Takeda does not apply in this situation because Takeda concerned a compound that was not disclosed in the prior art and that the closely related compound in the art was deemed to have negative qualities for the desired use. The Examiner further alleges in Takeda, two decisions were required: “selecting the prior art compound as a lead compound even though it had been described as an inferior compound related to several related antidiabetic compounds” and “modifying the prior art compound by altering its chemical structure.” (emphasis maintained) The Examiner further alleges that in the instant situation, the skilled artisan need merely select “the claimed compound from a number of compounds disclosed to be equally pertinent to the treatment of cancer” and use “this compound without any further chemical modification in an anticancer method in place of another compound having the exact same biological activity. (ras inhibition).” The Examiner concludes that because the steps that allegedly allow the skilled artisan to practice the instant invention are “much less radical and more predictable than those necessary in the situation described in Takeda”, the instant invention is obvious in light of Gordon and Rybak.

Applicants respectfully maintain that Takeda still supports the argument that “[r]ather than identify predictable solutions [for antidiabetic treatment], the prior art disclosed *a broad selection of compounds any one of which* could have been selected as a lead compound for further investigation.” (emphasis added) Also, as cited in the previous reply, in *Boston Scientific v Johnson & Johnson* (No. C 02-00790, 2007 WL 2408870 at \*13-14 (N.D. Cal. Aug. 21, 2007)), a passing reference to a possible solution does not necessarily imply that it is a viable solution.

Applicants respectfully submit that all of the thousands of prophetic compounds of Gordon, the forty synthesized FTI compounds of Gordon *and* the thousands of prophetic FTI compounds presented by Rybak provide “a broad selection of compounds any one of which” is little more than a passing reference to a possible solution for the skilled artisan searching for a farnesyl transferase inhibitor to combine with an

anthracycline. Gordon and Rybak disclose thousands of FTI compounds and as such, provide no guidance to select the particular FTI/anthracycline combination of claim 17.

2C. Request for withdrawal of rejection of claim 17 under 35 U.S.C. § 103(a)

Applicants submit that, for reasons cited above, claim 17 is in no way made obvious by Gordon in light of Rybak. Applicants request the reconsideration and withdrawal the rejection of claim 17 under 35 U.S.C. § 103(a).

**3. Claim Rejections – 35 U.S.C. § 103(a)**

3A. Rejection of claims 22, 26, 31 and 32 under 35 U.S.C. 103(a)

On pages 8-10 of the instant Action, the Examiner maintains the rejection of claims 22, 26, 31 and 32 under 35 U.S.C. § 103(a) as being unpatentable over Gordon in light of Rybak in further view of Porter *et al.* (Acta Otolaryngol, 1994, 114:105; referred to hereinafter as "Porter"). The complete details of the Examiner's comments are found on pages on pages 8-10 of the instant Action and are not reiterated in full in this reply.

Applicants respectfully submit that cancellation of claims 22, 26, 31 and 32 render moot this rejection.

Reconsideration of the instant Office Action, entry of the amendments submitted herewith, and allowance of all pending claims are respectfully requested. Prompt and favorable action is solicited.

Respectfully submitted,

Date: 9-15-09

Pamela C. Ball

Pamela C. Ball  
Agent for Applicant(s)  
Reg. No. 53,963

Biomeasure, Incorporated  
27 Maple Street  
Milford, MA 01757-3650  
(508) 478-0144 Telephone  
(508) 473-3531 Facsimile